COOK INCORPORATED
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MAY 2 1 2014

510(k) Summary – K140169
Vital-Port® CT Vascular Access System
21 CFR §807.92
Date Prepared: April 22, 2014

1. Submitter Information:

Applicant: Cook Incorporated
750 Daniels Way
P.O. Box 489
Bloomington, IN 47404
Phone: 724-845-8621 Ext. 2225
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Contact: Thomas J. Kardos
Email: Thomas.Kardos@cookmedical.com
Contact Address: Cook Incorporated
1186 Montgomery Lane
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Phone: 724-845-8621 Ext. 2225
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2. Device Information:

Trade name:	Vital-Port® CT Vascular Access System
Common name:	Port & Catheter, Implanted, Subcutaneous, Intravascular
Classification:	Class II
Regulation:	21 CFR 880.5965
	Subcutaneous, implanted, intravascular infusion port and catheter
Product Code:	LJT - Port & Catheter, Implanted, Subcutaneous, Intravascular

3. Predicate Device:

The Vital-Port® CT Vascular Access System is substantially equivalent to the following 510(k) cleared devices manufactured by Cook Vascular Incorporated;

Vital-Port® Vascular Access System Power Injectable Port, K081425.

4. Device Description:

The Vital-Port® CT Vascular Access System consists of a plastic port body and catheter lock. There are two Vital-Port® CT body sizes, Standard and Petite.

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The catheters offered are: 7.5 or 9.5 Fr. silicone catheters or 6.0 or 7.5 Fr. polyurethane catheters. All catheters are 50 cm in length and are supplied either pre-attached or detached.

Table 1: Vital-Port® CT Vascular Access System Configurations

Device Name	Catheter Size and Material	Maximum Flow Rate*	Injection Pressure Limit Setting
Standard Vital-Port® CT	9.5 Fr silicone	5 ml/sec	325 psi
	7.5 Fr silicone	5 ml/sec	325 psi
	7.5 Fr polyurethane	5 ml/sec	325 psi
	6.0 Fr polyurethane	5 ml/sec	325 psi
Petite Vital-Port® CT	7.5 Fr silicone	5 ml/sec	325 psi
	7.5 Fr polyurethane	5 ml/sec	325 psi
	6.0 Fr polyurethane	5 ml/sec	325 psi

*Flow rates were achieved using a room temperature infusate equivalent to Omnipaque 300® and a Medrad Injector. Omnipaque 300® has a viscosity of 11.8 centipoise at room temperature (20 degrees C). A change in the temperature or viscosity of the media will result in a change in achievable flow rate. Omnipaque 300® is a registered trademark of GE Healthcare.

5. Intended Use:

The Vital-Port® CT Vascular Access System is indicated for patient therapy requiring repeated vascular access for injection or infusion therapy and/or blood sampling. When used with a power injectable infusion set, Vital-Port® CT Vascular Access Systems are indicated for power injection of contrast media. The maximum pressure limit setting for power injectors used with the Vital-Port® CT may not exceed 325 psi, and the flow rate may not exceed the indicated maximum flow rate.

6. Comparison to Predicates:

It has been demonstrated that the Vital-Port® CT Vascular Access System is comparable to the predicate device in terms of intended use, duration of use, principles of operation, technological characteristics, insertion method, anatomical location, and method of sterilization.

7. Technological Characteristics:

The Vital-Port® CT Vascular Access System is a single lumen, long-term implantable infusion port catheter intended for in patient therapy requiring repeated vascular access, infusion therapy, power injected diagnostic techniques using contrast media and blood infusion/withdrawal.

The Vital-Port® CT Vascular Access System port body is available in two configurations, Standard and Petite, with either a pre-attached or detached silicone or polyurethane catheter.

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To demonstrate reliable design and performance of the Vital-Port® CT Vascular Access System, the following verification testing was performed:

- Dynamic Failure Flow Test – Testing demonstrated that the vital port did not fail during simulated use.
- Instantaneous Burst Test – Testing demonstrated that the burst test of the port system met the acceptance criterion.
- Static Burst Test – Testing demonstrated that the static failure pressure was at or above the acceptance criterion.
- Puncture Life Test – Testing demonstrated that the puncture life test met the acceptance criterion.
- Cyclic Test – Testing demonstrated that the cyclic test met the acceptance criterion
- MR Safety – Testing demonstrated that the Vital-Port® CT Vascular Access System is MR Conditional.
- Biocompatibility – Tests of cytotoxicity, sensitization, intracutaneous reactivity, acute systemic toxicity, subacute toxicity, genotoxicity, implantation, and hemocompatibility demonstrated the Vital-Port® CT Vascular Access System to be biocompatible. In conformance with the applicable sections of ISO 10993-1:2009, the predetermined acceptance criteria were met.

The results of these tests support a conclusion that the Vital-Port® CT Vascular Access System is as safe and as effective as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 21, 2014

Cook, Incorporated
Mr. Thomas J. Kardos
Vice President, Quality Assurance and Regulatory Affairs
750 Daniels Way
Bloomington, IN 47404

Re: K140169
Trade/Device Name: Vital-Port® CT Vascular Access System
Regulation Number: 21 CFR 880.5965
Regulation Name: Subcutaneous, Implanted, Intravascular Infusion Port And Catheter
Regulatory Class: II
Product Code: LJT
Dated: April 22, 2014
Received: April 23, 2014

Dear Mr. Kardos:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K140169

Device Name
Vital-Port® CT Vascular Access System

Indications for Use *(Describe)*
The Vital-Port® CT Vascular Access System is indicated for patient therapy requiring repeated vascular access for injection or infusion therapy and/or blood sampling.

When used with a power injectable infusion set, Vital-Port® CT Vascular Access Systems are indicated for power injection of contrast media. The maximum pressure limit setting for power injectors used with the Vital-Port® CT may not exceed 325 psi and the indicated maximum flow rate.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Digitally signed by
Richard C.
Chapman
Date: 2014.05.21
13:55:29 -04'00'